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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,508	03/01/2004	Terry B. J. Kuo	1970-10	1053

7590

07/25/2005

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EXAMINER

GREENE, DANA D

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,508

Applicant(s)

KUO ET AL.

Examiner

Dana D. Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-14, and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hoium et al. (US 6,512,945, hereinafter "Hoium"). Hoium is considered to disclose:

capturing an electrocardiogram signal of a person (see col. 1, ln. 50-53 and col. 18, 5-25, Hoium). The disclosed method of sensing cardiac signals is considered to anticipate the claimed method of capturing an electrocardiogram signal because both are the initial and necessary step in analyzing heart rate variability;

performing an analog-to-digital conversion of the electrocardiogram signal (see col. 15, ln. 20-45, Hoium). The analog to digital converter 208 as taught by Hoium is considered to anticipate the claimed A to D converter because both are connected to the signal amplifier for digitizing the electrocardiogram signal so that it can be entered into the computer;

selecting peaks of the electrocardiogram signal; calculating a standard deviation of heights or durations of the peaks; removing the peaks whose heights or durations exceed a first predetermined standard deviation; performing sampling and interpolation of qualified peaks to form consecutive peak signals; and performing spectrum analysis

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upon the consecutive peak signals in frequency domain (see col. 22, ln. 12-18 and col. 26, ln. 57-67, Hoium). The disclosed method of measurement after a particular peak is considered to anticipate the claimed peak selection because both involve a calculation of peak intervals, sampling and interpolating the qualified peaks to form a consecutive peak signal, and performing spectrum analysis to the peak signal in frequency domain.

Referring to claim 2, Hoium is considered to disclose:

the heart rate variability analytical method, wherein the first predetermined standard deviation is substantially equivalent to three standard deviations (see col. 8, ln. 43-52, Hoium). The disclosed standard deviation is considered to anticipate the claimed standard deviation because both advocate the setting of the first predetermined standard deviation to three standard deviations.

With reference to claims 3-5, Hoium is considered to teach:

the step of calculating peak-to-peak intervals of the electrocardiogram signal and filtering out unqualified peak-to-peak intervals (see col. 11, ln. 18-62, Hoium). The disclosed step is considered to anticipate the claimed method of filtering because both involve filtering out noise by means of statistical method, in order to enhance the precision of the analysis of heart rate variability.

Regarding claim 7, Hoium is considered to disclose:

a step of checking whether the sampling data is sufficient (see col. 6, ln. 61-65, Hoium). The disclosed sampling of R-wave to R-wave intervals is considered to anticipate the claimed step of sampling checking because both steps are performed to acquire the heart rate variability.

Referring to claim 9, Hoium is considered to disclose:

the heart rate variability analytical method of claim 1, wherein the peaks are QRS waves (see col. 21, ln. 35-50, Hoium). The disclosed QRS complex is considered to anticipate the claimed QRS wave because both are peaks of the electrocardiogram signal and stand for each heart beat.

With reference to claim 10, Hoium is considered to disclose:

an electrocardiogram signal detector capturing electrocardiogram signals of a person; a signal amplifier amplifying the electrocardiogram signals (see col. 1, ln. 50-53 and col. 15, ln. 45-50, Hoium). The disclosed detecting and amplifying means are considered to anticipate the claimed invention's signal detector and amplifier because both combinations are incorporated into the system for capturing the electrocardiogram signal of a person and for amplifying the electrocardiogram signal;

an analog-to-digital converter digitizing the electrocardiogram signals (see col. 15, ln. 20-45, Hoium). The disclosed analog to digital converter 208 is considered to anticipate the claimed A to D converter because both are connected to the signal amplifier for digitizing the electrocardiogram signal so that it can be entered into the computer;

a computer calculating, filtering, and analyzing the digitized electrocardiogram signal (see col. 6, ln. 13-25 and col. 14, ln. 5-22, Hoium). The disclosed computer and average processing option is considered to anticipate the claimed configuration because both teach the use of a computer connected to the analog-to-digital converter with a program for calculating, filtering, and analyzing the digitized electrocardiogram

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signal and controlling the steps of the heart rate variability analysis. In this connection, the digital input/output device is connected to the computer as a user-machine communication interface of the heart rate variability analytical apparatus.

Referring to claims 6 and 11, Hoium is considered to disclose:

the digital input/output device connected to a button for driving the computer to calculate, filter, and analyze the digitized electrocardiogram signals (see col. 8, ln. 1-16, Hoium). The disclosed button icon is considered to anticipate the claimed button because both control the operation of functions performed by the computer.

With regards to claims 12 and 13, Hoium is considered to teach the signal amplifier, A to D converter, computer and digital input/output device installed in a case and with one indicator for showing the status (see col. 8, ln. 10-16 and col. 15, ln. 20-45, Hoium).

Referring to claim 14, Hoium is considered to disclose:

a display 23 connected to the computer (see col. 8, ln. 10-16, Hoium). The disclosed display 23 is considered to anticipate the claimed display because both display the findings of the heart rate variability analysis of the electrocardiogram signals.

Regarding claim 16, Hoium is considered to disclose:

the electrocardiogram signal detector comprised of at least two electrodes (see col. 1, ln. 58-60, Hoium). The disclosed combination of electrodes is considered to anticipate the claimed use of at least two electrodes because both configurations teach the use of multiple electrodes to detect electrocardiogram signals of a person.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hoium. Hoium is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed printer. It would have been an obvious matter of design choice to use the teachings of Hoium with a printer in order to communicate the findings of the heart rate variability analysis of the electrocardiogram signals to the user.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

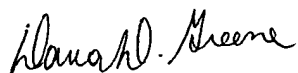
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene

